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10/550,224	05/02/2006	Satoshi Miyata	KOD182B.001APC	7803

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EXAMINER

EBRAHIM, NABILA G

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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12/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/550,224	Applicant(s) MIYATA ET AL.	
	Examiner Nabila G. Ebrahim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 3, 7-10, 15-17, and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 3, 7-10, 15-17, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The office action dated 8/29/07 has been herein vacated for not considering the preliminary amendments.

Election/Restrictions

1. Newly submitted claims 21-23 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are directed to treating wrinkles by oral administration of silymarin. The subject matter of "treating wrinkles orally by promoting the production of elastin" is independent from the Group for a composition comprising silymarin and the Group for treating wrinkles by topical administration of silymarin included in this group of claims will require a different search. In addition, treating wrinkles can be performed using many different compositions and methods such as using royal jelly. (see for example US publication 20040176453 that disclosed treating skin wrinkles by oral administration to such person of an effective amount of at least one water-soluble amino acids represented by formula (I) $X-C_{nH_{2n}}-CR(NH_2)COOH$ (1) wherein X represents a hydrogen atom (H) or a carbamoyl group ($CONH_2$), R is hydrogen or a methyl (CH_3) group, and n is a whole number from 1 to 4.)

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-4, 6-10, and 13-16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haratake JP 2000-169328, machine translation is provided (Haratake) in view of Candau et al. US publication 20020064507 (candau) and further in view of Benaiges et al. Study of the refirming effect of a plant complex, International Journal of Cosmetic Science Volume 20 Issue 4 Page 223-233, August 1998 in view of Sekimoto US 6814958 (Sekimoto).

Haratake teaches a composition including an extract from a plant of the genus *Silybum* of the family Compositae, e.g. *Silybum marianum* in an amount of preferably 0.0001-2.0 wt.% based on the enhancer. In the extract, silymarin, silybin, silychristin and silydianin, or the like, as active substances are present alone or as a mixture. The extraction from the whole herb of the plant or an individualized material such as leaf, a stem or a fruit is preferably carried out with an organic solvent, or the like, having an intermediate polarity such as a lower alcohol, a lower polyhydric alcohol, e.g. propylene glycol (abstract). The preparation is an external cosmetic (0009). Haratake used a lower polyhydric alcohol such as propylene glycol.

Note that the recitation of the intent of use of the claimed composition “for treating wrinkles on the skin” and “preventing skin aging” have not been given patentable weight, because the prior art compositions would be at least capable of performing said use. It is also noted that the amount of silymarin included in the composition of the prior art of 0.0001-2.0% overlaps with the amount recited in the instant claims of 0.7-2.0%.

Haratake teaches the use of a lower polyhydric alcohol. However, the reference is deficient in disclosing literally dipropylene glycol as the solvent.

Candau et al. teaches that the plant flavylum comprised in a cosmetic preparation comprising can be extracted by using a solvent such as propylene glycol or dipropylene glycol (claim 30).

Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to use either of the organic solvents to be used in a topical cosmetic preparation since the art knew the compounds as equivalents.

Haratake is also deficient in teaching the use silymarin to treat wrinkles.

Benaiges disclosed a study of the refirming effect of a plant complex and teaches that one way to prevent such a loss of elasticity is to use active ingredients that are able to inhibit elastase enzymes. A plant complex was prepared using the following plants: lady's thistle (*Silybum marianum* GAERTN), alchemilla or yarrow (*Alchemilla vulgaris* L.), horsetail (*Equisetum arvense* L.) as well as germinated seeds (*Glycine soja* Siebold and Zucc., *Triticum vulgare* Vilars, *Medicago sativa* L., *Raphanus sativus* L.). The complex was standardized to give the corresponding active principles; silybin, tannins, silicon and peptides, respectively, and in vitro enzymatic tests were carried out to establish its ability to inhibit elastase. The study of enzymatic inhibition was carried out using two enzymes: (1) porcine pancreatic elastase (PPE), and (2) human leukocyte elastase (HLE). The results showed that the plant complex presents non-competitive inhibition in the order of 41.0% against PPE and 50.0% against HLE. An in vivo test was made alongside the in vitro test using an SEM 474 Cutometer (Courage & Khazaka) to study the elasticity of the skin, and positive effects were obtained when applying a cosmetic formulation containing 5% of the plant complex. Image analysis of duplicates of the cutaneous surface, before and after treatment began with a product containing 5% of plant complex and showed that wrinkles were decreased by 36.7% (abstract). Note that HLE is the enzyme responsible for breaking elastin and since the effect of the potanical extract inhibited the effect of HLE by 50%, it is expected that the increase of elastin is doubled as required by claim 20.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Haratake's composition in the method disclosed by Beniges to

refirm the skin and treat wrinkles. The expected results would be a topical cosmetic preparation comprising silymarin, which is used for anti-aging purposes.

Declaration under 37 C.F.R. § 1.132

3. The declaration under 37 CFR 1.132 filed 7/22/2008 is insufficient to overcome the rejection of claims 1-4, 6-10, and 13-16 and 20 based upon 35 USC §103 as set forth in the last Office action because:

- The affidavit does not provide a side by side comparison of the composition and method of the prior art compared the composition and method of the instant claims to show the unexpected results obtained by the instant claims.
- The experiments performed are based only on oral administration of a capsule containing silymarin and do not address the topical composition on which the scope of claims as amended encompass. Note that instant claims do not recite capsules.
- The composition used comprises grapeseed oil which is known to have benefits to the skin and has been used in different cosmetics including anti-wrinkle compositions. Thus, it is not clear if the results obtained are limited to silymarin or grapeseed oil is a factor in these results.
- The amount of silymarin used as shown in the table in page 2 is about 0.4% of the total composition (without the capsule), while the claim has a range that starts at 0.7%.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-10, and 13-16 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments are based on the deficiency of the prior art relied upon in the last office action in disclosing a solvent such as newly recited dipropylene glycol. However, in view of relying upon Haratake in view of Candau, the arguments are rendered moot.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit
1618